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TOWNSEND AND TOWNSEND AND CREW, LLP (018563)			MEINECKE DIAZ, SUSANNA M	
TWO EMBARCADERO CENTER, EIGHTH FLOOR			ART UNIT	
SAN FRANCISCO, CA 94111-3834			PAPER NUMBER	
			3623	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/621,716

Applicant(s)

SEPE, CHRISTOPHER THOMAS

Examiner

Susanna M. Diaz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This final Office action is responsive to Applicant's response filed June 22, 2006.

No claims have been amended.

Claims 1-20 are presented for examination.

### ***Response to Arguments***

2. Applicant's arguments filed June 22, 2006 have been fully considered but they are not persuasive.

Applicant argues the following:

...As both the Bianco and the McMenimen publications were filed after the filing date of the present application, neither of these publications qualify as prior art. Thus, Applicant respectfully submits that the present rejections must be withdrawn.

Applicant recognizes that each of these publications has a corresponding provisional application which was filed prior to the filing date of the present application. Applicant notes that the provisionals are quite different than the published applications. While Applicant concedes that the disclosures of these provisional applications might be relied on under certain circumstances, to do so the Examiner must point to relevant disclosure in the provisional text. Applicant further wishes to point out that while the provisional application underlying the McMenimen et al. publication was incorporated into that publication by reference, the provisional application underlying the Bianco publication does not appear to have been incorporated by reference. A word search of the publication fails to show an incorporation by reference. Thus, with respect to Bianco et al., the Examiner not only cannot rely on the provisional text as prior art, but must instead find teachings which appear both in the published Bianco application and in the provisional application. (Page 2 of Applicant's response)

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The Examiner has established a *prima facie* case that claims 1-20 are unpatentable over Bianco et al. (US 2002/0082865) in view of McMenimen et al. (US 2002/0077850) under 35 U.S.C. 103(a). The fact that both Bianco and McMenimen claim priority to their respective provisional applications means that Bianco and McMenimen are potentially granted a § 102 date back to the filing date of their respective provisional applications (for purposes of applying them as prior art). Furthermore, even if all of the subject matter of a non-provisional application is not fully disclosed in a provisional application to which the non-provisional claims priority, the subject matter that *is* fully supported by the provisional application is granted priority back to the filing date of the provisional application (i.e., a continuation-in-part type of analysis is used to assess the granted priority date for the disclosed subject matter in the non-provisional application). As a matter of fact, the Examiner did point out support in the provisional application of McMenimen for the teachings relied upon in the art rejection. Applicant has not established which part of the disclosure of Bianco or McMenimen **relied on in the art rejection** of the claims in the instant application are allegedly not supported by the respective provisional applications of both Bianco and McMenimen; therefore, Applicant's arguments are not persuasive.

Furthermore, Examiner notes that, as per MPEP § 2144.03(C), the statements of Official Notice made in the art rejection have been established as admitted prior art since Applicant has not traversed the Examiner's assertions of Official Notice. More specifically, the following statements are now established as admitted prior art:

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(1) Official Notice is taken that it is old and well-known in the art of medical devices that dental appliances are commonly ordered build-to-order medical products.

(2) Official Notice is taken that it is old and well-known in the art of manufacturing to alert manufacturing personnel when a manufacturing stage falls behind schedule.

(3) Official Notice is taken that it is old and well-known in the art of manufacturing to alert a customer to manufacturing slippage, i.e., that a manufacturing stage has fallen behind schedule.

(4) Official Notice is taken that it is old and well-known in the dental industry for a dentist or orthodontist to install dental appliances.

In summary, Applicant's arguments are non-persuasive and the art rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bianco et al. (US 2002/0082865) in view of McMenimen et al. (US 2002/0077850).

Regarding claims 1 and 20, Bianco discloses a patient scheduling system in which patients can access a personal account online to receive task reminders,

schedule medical appointments, purchase a medical product, etc. (§§ 16-22). Since each patient must log in, there are presumably a plurality of patients and patient computers connected to the network (Figs. 1, 4; ¶ 97), which may be a wide area network (¶ 81). Bianco states that “the medical event may be an operation...but should be understood generally to encompass any type of medical events” (¶ 78). When a patients logs in to the system, he/she may be reminded to complete various pre-procedure or post-procedure tasks, such as scheduling an appointment, scheduling the procedure, or ordering a medical product (§§ 94, 95, 108, 117, 121, 140). Appointment reminders may also be requested (§§ 108, 140) and messages may be sent to the patient’s e-mail inbox (¶ 109). While Bianco reminds patients to order medical products and schedule appointments or medical procedures, Bianco does not expressly integrate the scheduling with the manufacturing process. However, the Examiner submits that when a scheduled procedure requires installation, insertion, or some other use of an ordered medical product, then the medical product must be made available in time for the scheduled procedure. In other words, there must be some understanding of whether a needed medical product will be available in time for the related medical procedure. While this practice (i.e., checking to make sure all supplies are ready for a medical procedure) was commonly performed by hand, McMenimen incorporates by reference the full disclosure of Provisional Patent Application No. 60/180,289 (to which McMenimen claims priority). In the provisional application, McMenimen describes an automated inventory monitoring system in which the “patient and/or the ordering entity can monitor the status of the build process, expected completion, and shipment delivery

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status" (page 2 of the section entitled "Responsive Manufacturing and Inventory Control"). Since it is well-known for medical procedures to be delayed until necessary medical products become available and McMenimen describes an automated system for alerting patients and ordering entities to the status of build-to-order, implantable medical devices, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify Bianco to allow a logged-on patient to receive manufacturing progress information with the patient computer and perform patient scheduling over a wide area network when one or more dental appliances reach a predetermined manufacturing progress in order to more efficiently facilitate scheduling of a medical procedure when needed build-to-order medical devices are expected to become available, thereby mitigating wastes in time and effort that might otherwise be spent rescheduling medical procedures when the delivery of required medical devices is delayed. It should be noted that "predetermined manufacturing progress" could refer to any part of the manufacturing process, including the beginning, an intermediate stage, and the end (i.e., the product is completed). McMenimen shows that the patient and/or ordering entity can track the device anytime during the build process, including expected completion, which is an example of "predetermined manufacturing progress."

Further regarding claims 1 and 20, neither Bianco nor McMenimen expressly teaches that the medical product comprises one or more dental appliances; however, Official Notice is taken that it is old and well-known in the art of medical devices that dental appliances are commonly ordered build-to-order medical products. The claimed

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functionality and that of Bianco and McMenimen would be the same regardless of what type of device is manufactured for the patient; therefore, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to adapt the Bianco-McMenimen combination to supply one or more dental appliances in order to expand its customer base to the dental industry. Additionally, the limitations regarding the dental industry and dental appliances *per se* merely recite various intended uses of the invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The claimed recitations of intended use neither result in a structural difference between the claimed invention and the prior art nor in a manipulative difference as compared to the prior art; therefore, the claimed invention is not deemed to be patentably distinct over the prior art.

As per claims 2-5, Bianco's server can generate reminders and e-mail messages for the patients while McMenimen apprises the patient and ordering entity of medical device manufacturing status (as discussed above). More specifically, McMenimen allows patients and ordering entities to access manufacturing progress information [Claim 2] when the appliances reach a predetermined manufacturing stage (page 2 of the section entitled "Responsive Manufacturing and Inventory Control"), [Claim 3]



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wherein the appliances are marked as part of the manufacturing process (page 2 of the section entitled "Responsive Manufacturing and Inventory Control"), [Claim 4] when the appliances reach one or more intermediate stages of manufacturing (page 2 of the section entitled "Responsive Manufacturing and Inventory Control"), [Claim 5] wherein the information is related to manufacturing progress (page 2 of the section entitled "Responsive Manufacturing and Inventory Control"). The Examiner further submits that a device ordering entity is often a treating professional since the treating professional will likely be installing the device. Therefore, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to adapt the Bianco-McMenimen combination such that the server sends a message to a patient when the appliances reach a predetermined manufacturing stage (claim 2), wherein the server sends a message to a patient when the appliances are being marked (claim 3), wherein the server sends a message to a treating professional when the appliances reach one or more intermediate stages of manufacturing (claim 4), wherein the server sends an electronic mail message to transmit information relating to manufacturing progress (claim 5) in order to more efficiently facilitate scheduling of a medical procedure when needed build-to-order medical devices are expected to become available, thereby mitigating wastes in time and effort that might otherwise be spent rescheduling medical procedures when the delivery of required medical devices is delayed.

Regarding claim 6, Bianco discloses that the server maintains calendar pages for the treating professionals (Figs. 5-6B; ¶¶ 81, 97, 98).

As per claim 7, Bianco's server invites a patient to access an on-line calendar and schedule an appointment (§§ 94, 95, 108, 117, 121, 140); however, Bianco does not expressly send such an invitation or reminder when the appliances reach the last stage of manufacturing. As discussed above, it is well-known for medical procedures to be delayed until necessary medical products become available and McMenimen describes an automated system for alerting patients and ordering entities to the status of build-to-order, implantable medical devices. Therefore, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to adapt the Bianco-McMenimen combination to invite a patient to access an on-line calendar and schedule an appointment when the appliances reach the last stage of manufacturing in order to more efficiently facilitate scheduling of a medical procedure when needed build-to-order medical devices are expected to become available, thereby mitigating wastes in time and effort that might otherwise be spent rescheduling medical procedures when the delivery of required medical devices is delayed.

Regarding claim 8, Bianco discloses a network of treating professionals coupled to the network (Figs. 5-6B; §§ 81, 97, 98).

Regarding claim 9, neither Bianco nor McMenimen explicitly teaches that the server requests intervention from manufacturing personnel when one or more manufacturing stages fall behind schedule; however, Official Notice is taken that it is old and well-known in the art of manufacturing to alert manufacturing personnel when a manufacturing stage falls behind schedule. This allows the personnel to make decisions that could rectify manufacturing delays, as needed. Such intervention might

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be especially crucial in high risk or emergency medical situations. Therefore, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to adapt the Bianco-McMenimen combination such that the server requests intervention from manufacturing personnel when one or more manufacturing stages fall behind schedule in order to allow manufacturing personnel to make decisions that could rectify manufacturing delays, as needed (e.g., in high risk or emergency medical situations).

Regarding claim 10, while the Bianco-McMenimen combination teaches that the server updates the patient with manufacturing progress information (as discussed above), the combination does not expressly teach the specific data recited in the claim (i.e., information relating to a delay caused by manufacturing slippage). This difference is only found in the non-functional descriptive material and is not functionally involved in the steps recited nor does it alter the recited structural elements; therefore, such a difference does not effectively serve to patentably distinguish the claimed invention over the prior art. The recited method steps would be performed the same regardless of the specific data. Further, the structural elements remain the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP § 2106. Nevertheless, Official Notice is taken that it is old and well-known in the art of manufacturing to alert a customer to manufacturing slippage, i.e., that a manufacturing stage has fallen behind schedule. This allows the customer to

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make product-related decisions or alternate plans accordingly. For example, some sort of intervention or alternate planning might be especially crucial in high risk or emergency medical situations. Therefore, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to adapt the Bianco-McMenimen combination such that the server updates the patient with information relating to a delay caused by manufacturing slippage in order to allow the patient to make product-related decisions or alternate plans, as needed (e.g., in high risk or emergency medical situations).

[Claims 11-19] Claims 11-19 recite limitations already addressed by the rejection of claims 1-10 above; therefore, the same rejection applies.

Furthermore (regarding claim 7), as discussed in the rejection of claim 1 above, Bianco's patients log on to the system.

Regarding claim 18 and as discussed in the rejection of claim 1 above, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to adapt the Bianco-McMenimen combination to supply one or more dental appliances in order to expand its customer base to the dental industry. Additionally, Official Notice is taken that it is old and well-known in the dental industry for a dentist or orthodontist to install dental appliances. Therefore, the Examiner submits that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to market the Bianco-McMenimen combination to

treating professionals, including dentists or orthodontists, in order to expand its customer base to the treating professionals in the dental industry.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna M. Diaz whose telephone number is (571) 272-6733. The examiner can normally be reached on Monday-Friday, 10 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tariq Hafiz can be reached on (571) 272-6729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Susanna M. Diaz  
Primary Examiner  
Art Unit 3623

July 3, 2006